Chapter 8: Regulations and Associated Publix Policies

Overview

Introduction

This chapter details various legal guidelines and procedures by which Publix Pharmacy associates must abide.

In this chapter

This chapter contains the following topics.

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Overview, Continued

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Code of Ethics for Pharmacy Associates

Introduction

Publix supports the *American Pharmacists Association's Code of Ethics* and expects our pharmacists to abide by the principles stated in it. This *Code of Ethics*, prepared and supported by pharmacists, states the principles that form the moral obligations that guide pharmacists in their relationships with patients, health professionals, and society.

Additionally, Publix has adopted its own Code of Ethics. In order to successfully carry out Publix's mission, all pharmacy associates must adhere to Publix's Code of Ethics.

APhA *Code of Ethics*

The American Pharmacists Association (APhA) declares the following *Code of Ethics*.

- *A pharmacist respects the covenantal relationship between the patient and pharmacist.* Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.
- *A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.* A pharmacist places concern for the wellbeing of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.
- *A pharmacist respects the autonomy and dignity of each patient.* A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.
- *A pharmacist acts with honesty and integrity in professional relationships.* A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.
- *A pharmacist maintains professional competence.* A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

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Code of Ethics for Pharmacy Associates, Continued

APhA *Code of Ethics*, cont'd

- *A pharmacist respects the values and abilities of colleagues and other health professionals.* When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.
- *A pharmacist serves individual, community, and societal needs.* The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.
- *A pharmacist seeks justice in the distribution of health resources.* When health resources are allocated, the pharmacist is fair and equitable, balancing the needs of patients and society.

Publix *Code of Ethics*

At Publix, we are committed to conducting our business with the highest standards of integrity. Our associates, customers, stockholders, suppliers, and communities expect us to uphold high standards of ethical behavior. The Publix *Code of Ethics* provided at Orientation, in the Associate Handbook and in the Managers' Reference Library is intended to give associates a guide to the ethical standards we must maintain. Publix is committed to complying to all applicable laws and we expect our associates to do so, as well as comply to company policy and procedures. Each year our associates attest to understanding and conducting themselves in accordance with our Code of Ethics, including following our Conflict of Interest policy.

Confidentiality

Introduction

All Pharmacy associates must have an understanding of the need for confidentiality regarding our patients' medical records.

Customer prescriptions contain private, personal information. You must respect the privacy of our customers to maintain their trust and to comply with legal and ethical standards.

Policy

All information pertaining to patients must be maintained in the strictest confidence. Never disclose any patient information to anyone outside the Pharmacy unless specifically authorized by the Pharmacist in charge. Any disclosure, even to other associates within the Pharmacy, will be strictly on a need-to-know basis.

Any Publix associate who has access to a patient's medical records is required to have a signed *Confidentiality Agreement* and an *Information Resources Policy* filed in his or her Personnel File Folder.

Protected health information (PHI)

All Pharmacy associates must take every reasonable precaution to safeguard a patient's protected health information (PHI), including oral information, from any intentional or unintentional uses or disclosures, when providing treatment, collecting payment for treatment, and conducting certain health care operations. See *Chapter 7* for more information on PHI.

Patient Social Security Numbers

Never add a patient's Social Security Number to the pharmacy system. We do not use the SSN for processing prescriptions and it is in the best interest of our patient's privacy to avoid storing unnecessary personal information.

Handling of records

Consider these confidentiality rules.

- Never copy or remove records of patient information from the premises except as specifically authorized by the Pharmacist in charge.
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides rules governing the use and disclosure of protected health information (PHI). See *Chapter 7* for more details on *HIPAA* and *PHI*.
- Records may be released pursuant to a valid subpoena. (See the *Handling Requests to Access Records (PHI)* section in *Chapter 7* for more information.) However, in no event may records which would disclose patient information regarding AIDS, HIV, or sexually transmitted diseases be released pursuant to a subpoena.
- Records may be released pursuant to a valid authorization. (See the *Handling Requests to Access Records (PHI)* section in *Chapter 7*)
- State laws may contain restrictions on uses and disclosures of PHI.

Conscientious Objection

Introduction

Some Pharmacists may have a conscientious objection to filling certain prescriptions (for example, abortifacient and contraceptive drugs). Publix policy addresses this circumstance.

Policy

Every Pharmacist has the right to refuse to dispense a prescription based on religious, moral, or ethical grounds. However, as part of our policy, Publix customers must be accommodated and be able to receive any prescription product that's legally prescribed by a physician. Publix will have on staff in each Pharmacy a dispensing Pharmacist who's able to serve all of our customers.

Notification

Any Pharmacist who is a conscientious objector must notify the Pharmacy Supervisor of his or her position. This notification must be done *before* refusing to fill any customer's prescription on these grounds.

Publix's Policy Regarding Substance Abuse

Introduction

Publix is committed to providing and maintaining a working environment free of substance abuse. Substance abuse often leads to performance deficiencies, increased operating costs, and injuries to associates and their coworkers.

Publix is primarily concerned with substances that may affect an associate's mental or physical ability to function normally at work. It's important that associates understand Publix has designed preventative, as well as disciplinary, measures to maintain working environments free of substance abuse.

Prohibited conduct under Publix's Substance Abuse Policy

The following is prohibited under Publix's Substance Abuse Policy

- *selling* or distributing any drug, including a prescription drug, whether on or off duty, unless the associate is legally authorized to sell or distribute the substance in question under the circumstances
- *possessing* any illegal drug on Publix premises at any time
- *using* any illegal drug at any time (This includes out-of-date or expired prescription drugs, prescription drugs prescribed for someone else, or current prescription drugs not used according to the prescription. Medications over 24 months old are considered out-of-date when prescribed on an as needed basis.) and
- *drinking* alcohol while on the job or reporting to work under the influence of alcohol.

Drug Testing

Applicants that are offered a position at Publix are drug tested before they are hired. Associates working for Publix are subject to random drug testing. The method and location of testing are chosen by Publix.

Refusing to submit to testing is failing to

- appear for a test within the required timeframe
- remain at the collection site until the testing process is complete
- provide a specimen or cooperate with any part of the testing process or
- provide a sufficient amount of urine without a valid medical explanation.

Applicants who refuse to submit to testing will be ineligible for employment for one year. Associates who refuse to submit to testing should be terminated.

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Publix's Policy Regarding Substance Abuse, Continued

Prescription Documentation for Associates Working in Publix Pharmacy

Associates working in Publix pharmacies must follow these requirements regarding their own personal prescriptions.

- If you are taking a prescription medication, you MUST have a valid prescription for this product. The prescription must be for you and must be filled within State/Federal prescription date guidelines.
- If you are taking a PRN (non-routine) medication, make sure your prescription is NO MORE THAN 2 years old. Medications over 24 months old are considered out-of-date when prescribed on an as needed basis.
- If you are selected for a random drug screen and are taking a prescription medication, be prepared to produce a prescription bottle and/or a prescription that was written or has been filled within the last 24 months.
- Publix has a VERY STRICT no tolerance policy. If you are tested, found to be positive for a product, and do not have the above noted supporting documentation, you WILL NOT be allowed to work in the Pharmacy for a period of 3 years.

Prescription drugs and safety

An associate taking prescribed drugs must ensure that the use of the drugs doesn't affect his or her performance or his or her ability to perform assignments safely. If an associate feels prescribed drugs may affect his or her performance, safety, or the safety of others, then the associate should share these concerns with his or her manager, Retail Associate Relations Specialist, or a representative of the Employee Assistance Program (EAP) department so that accommodations may be considered. In some circumstances, it may be appropriate to request a note from the associate's physician stating that the associate is capable of safely performing job duties.

Additional Information or Questions

For more information on Publix's Substance Abuse Policy, see the *Managers' Reference Library* (*MRL*) or contact your Pharmacy Supervisor with any questions.

Pharmacist Liability Insurance

Introduction

Like many retailers and pharmacies, Publix self insures most of the financial risk associated with pharmacy quality related events and malpractice claims. In those situations in which Publix either resolves a claim or lawsuit or is found by a court or jury to be liable, Publix is fully responsible for any legal fees, settlement or verdict within its self–insured retention.

Defending and Indemnifying Publix Pharmacists

Publix will provide a legal defense and include the Pharmacist in any settlement or resolution of a claim involving allegations of a quality related event or malpractice as long as, in Publix' sole determination, the Pharmacist acted within the course and scope of his or her job duties, and did not engage in any intentional or negligent acts (or failures to act).

Publix will provide a legal defense and include the Pharmacist in any settlement or resolution of any other type of claim other than quality related events or malpractice as long as, in Publix' sole determination, the Pharmacist acted within the course and scope of his or her job duties.

These decisions are made by Publix on a case-by-case basis.

Pharmacists' Responsibility

If a Pharmacist's actions involving either a quality related event or malpractice results in a verdict against Publix or the settlement of a claim or lawsuit, Publix may seek contribution or indemnification from the individual Pharmacist or from any insurance policy maintained by an individual Pharmacist for any loss Publix suffers. Publix's decision to seek contribution or indemnification from any individual Pharmacist or his or her insurance company will be made on a case-by-case basis considering all the facts known to Publix at the time Publix might make such a request.

Pharmacists providing immunization in Florida and Georgia

Regardless of any other provision of this policy, Publix will indemnify and defend any associate for any claims arising out of or related to the pharmacist administrating vaccines permitted by Florida Statute 465.189 and Georgia O.C.G.A. 43-34-26.1 up to the limits specified by the statutes.

Hartford Excess Druggist Liability Insurance Policy

In addition to self insurance, Publix maintains an Excess Druggist Liability Insurance policy. Subject to the terms of the Policy, the Excess Druggist Liability Policy provides coverage to any associate acting within the scope of his or her employment while performing duties related to pharmacists' professional services. However such coverage only applies to the extent costs, fees, judgments or settlements paid by Publix exceed the self-insured retention.

Pharmacists' Liability Insurance

Publix does not purchase insurance which specifically covers individual Pharmacists in all situations. Many Pharmacists choose to carry their own personal, professional malpractice insurance.

Laws Impacting Pharmacy

Introduction

Each state has documented laws and rules pertaining to the practice of pharmacy. In addition to state laws, there are many federal regulations impacting pharmacy. All pharmacy associates must comply with these state and federal requirements to practice pharmacy.

State laws

Each state in which Publix operates a pharmacy has a governing Board of Pharmacy. The Board of Pharmacy has the authority to, but is not limited to

- adopt rules and implement the rules pursuant to any state or federal statute, rule, or regulation
- examine each applicant who has applied to the board for licensure and has completed certain requirements
- process the renewal of licenses
- apply and set fees and expenditures to applicants
- set and monitor professional pharmaceutical continuing education (CE) requirements
- adopt a Standard of Practice
- carry out any disciplinary action set forth by the state rules or regulations and
- inspect any pharmacy (in a lawful manner).

Federal laws

In addition to state laws, all pharmacies are required to comply with federal laws pertaining to the practice of pharmacy that include, but are not limited to

- the Federal Controlled Substance Act
- the Federal Food, Drug, and Cosmetic Act
- the Comprehensive Drug Abuse Prevention and Control Act
- the Omnibus Budget Reconciliation Act of 1990 (OBRA '90)
- the Affordable Care Act – Non-discrimination in Healthcare Programs and Activities,
- the Americans with Disabilities Act
- the Civil False Claims Act and
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Online access to laws

Each Publix Pharmacy is required by law to have access to applicable laws and rules. These laws and rules are located on the pharmacy portal page of Publix Connection – *References> Government/Agency* . Make sure the current laws, in addition to this *Pharmacy Reference & Procedures Guide*, are easily accessible to all Publix Pharmacy associates for easy reference as needed.

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Laws Impacting Pharmacy, Continued

Training on laws	Anytime an associate is registered with the state in some capacity, they are expected to maintain their knowledge of the laws as part of the responsibility of being a licensed professional. This includes continuing education requirements. In addition, Publix provides training regarding our policies and procedures associated with various federal and state regulations and further designs standard processes and protocols that associates must follow to ensure our compliance with state and federal regulations. This training is incorporated in new hire job class training.
Questions	If you have any questions about a pharmacy laws or rules, how to access these laws, or about the training you receive at Publix, please contact your Pharmacy Supervisor or divisional Pharmacy Operations Manager.

Pharmacist Responsibilities Regarding Supervision of Associates in the Pharmacy

Overview

In every pharmacy, the licensed pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns, registered pharmacy technicians, pharmacy technicians in training (FL only), and pharmcy clerks. This includes associates that are cross-trained in pharmacy with discretionary access. This responsibility includes, but is not limited to:

- supervising the day-to-day activities of all associates working in the pharmacy
- ensuring interns and technicians are only performing delegable tasks pursuant to state requirements
- ensuring all interns and technicians are properly registered according to the state's requirements
- ensuring all associates in the pharmacy are in the proper Publix uniform with proper identification as required by the state, and
- ensuring the number of technicians supervised by a pharmacist during any given shift meets the ratio requirements established by the state.

Pharmacy position qualifications

Each position in the pharmacy department has a supporting job class description in the Retail MRL on Publix Connection (*Resources > Human Resources > Retail MRL > Job Classes and Descriptions > Job Descriptions > Pharmacy*). The job class description identifies duties and responsibilities and minimum qualifications, as well as other job information. These descriptions also apply to someone who is cross-trained in any pharmacy job class.

Delegable and non-delegable technician tasks

A pharmacy technician may only assist a pharmacist in executing or carrying out the practice of the profession of pharmacy, but shall never themselves engage in the practice of the profession of pharmacy. Therefore, pharmacy technicians may only perform delegable tasks which are tasks performed pursuant to a pharmacist's direction, without the exercise of the pharmacy technician's own judgment and discretion, and which do not require the pharmacy technician to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

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Pharmacist Responsibilities Regarding Supervision of Associates in the Pharmacy, Continued

Delegable and non-delegable technician tasks, cont'd

Delegable tasks include:

- data entry
- labeling of preparations and prescriptions
- retrieval of prescription files, patient files and profiles, and other similar records pertaining to the practice of pharmacy
- the counting, weighing, measuring, and pouring of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system
- the initiation of communication to confirm the patient's name, medication, strength, quantity, directions, number of refills, and date of last refill
- the initiation of communication with a prescribing practitioner or their agents to obtain clarification on missing or illegible dates, prescriber name, brand or generic preference, quantity, license numbers or DEA registration numbers
- the acceptance of authorization to dispense medications pursuant to a prescribing practitioner's authorization to fill an existing prescription that has no refills remaining (refill authorization)
- organizing of or participating in continuous quality improvement related events, meetings, or presentations
- participation in a monitoring program to remove deteriorated pharmaceuticals to a quarantine area; and
- while under the direct supervision of the pharmacist, performance of any other mechanical, technical or administrative tasks which do not themselves constitute practice of the profession of pharmacy.

Non-delegable tasks or tasks that can only be performed by a pharmacist or an intern under the supervision of a pharmacist, include:

- receive new non-written prescriptions or receive any change in the medication, strength, or directions of an existing prescription
- interpret a prescription or medication order for therapeutic acceptability and appropriateness
- conduct final verification of dosage and directions
- engage in prospective drug review
- monitor prescription usage
- override clinical alerts without first notifying the pharmacist
- transfer a prescription
- prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written
- engage in patient counseling, and
- engage in any other act that requires the exercise of a pharmacist's professional judgment.

Note: South Carolina state certified technicians may be authorized to perform additional delegable tasks. Refer to your state's requirements if applicable.

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Pharmacist Responsibilities Regarding Supervision of Associates in the Pharmacy, Continued

Summary pharmacy technician requirements

Below is a summary of requirements for each state in which Publix operates regarding technician to pharmacist ratio, as well as registration and training requirements.

State	Technician to Pharmacist Ratio	Technician Registration
Alabama *(AL Administrative Code Chapter 680-X-2)*	3:1 Note: One technician must be nationally certified.	Must be registered before working in the pharmacy as a technician.
Florida *(FL Administrative Code 64B16-27.410 and 64B16-26.351)*	Retail pharmacy – 4:1 Central Fill pharmacy – 4:1 Central Processing – 6:1 Specialty Support – 6:1	Must be registered upon completion of a BoP-approved training program until which the technician is considered "in-training." Training period must not extend beyond 6-months.
Georgia *(Official Code of GA Chapter 26-4-82)*	3:1 Note: One technician must be nationally certified or certified through a program approved by the BoP.	Must be registered before working in the pharmacy as a technician.
North Carolina *(NC Administrative Code Section 90-85.15A)*	2:1 with option to increase to 3:1 Note: The increase is only with approval by the BoP and must include one nationally certified technician.	• Technicians not nationally certified must register within 30 days of completing a pharmacy training program. • A nationally certified technician must become registered upon certification.
South Carolina *(SC Code of Regulations Section 40-43-82 and 40-43-86)*	4:1 Note: A pharmacist may not supervise more than two non-state certified technicians.	Must be registered before working in the pharmacy as a technician.

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Pharmacist Responsibilities Regarding Supervision of Associates in the Pharmacy, Continued

Summary pharmacy technician requirements, cont'd

State	Technician to Pharmacist Ratio	Technician Registration
Tennessee *(TN Rules and Regulations Section 1140-02-.02)*	2:1 with option to increase to 4:1 Note: The increase is only with approval by the BoP and must include two nationally certified technicians.	Must be registered within 90-days of being in the job.
Virginia *(VA Regulations 18VAC110-20-270)*	4:1 Note: No more than four persons acting as pharmacy technicians.	Must be registered upon within in 9-months of hire by • passing the PTCB national certification exam OR • completion Publix Technician Basics (BoP-approved training program) and passing the ExCPT national certification exam.

For pharmacy technician entry-level training requirements, see Ch. 2, **Pharmacy Technician Basics Training Program**. Also, the entire technician training plan is located in Learning for reference, as well as the transcript for completion status.

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Pharmacist Responsibilities Regarding Supervision of Associates in the Pharmacy, Continued

Summary pharmacy intern requirements

In each state, but Tennessee, all interns must be licensed with the state. In Tennessee the intern must be enrolled or graduated from an ACPE accredited pharmay school. Most states allow one intern and one extern per pharmacist. Check your state laws and talk to your Pharmacy Supervisor prior to hiring an intern or accepting an extern on rotation.

For pharmacy intern entry-level training requirements, see Ch. 2, **Pharmacy Technician Basics Training Program**. Also, the entire intern training plan is located in Learning for reference, as well as the transcript for completion status.

Summary pharmacy clerk requirements

Pharmacy clerks perform many tasks in the pharmacy none of which are considered technician delegable tasks. These associates are not permitted to perform any technician duties and are not required to be licensed or registered with the state.

The Pharmacy Clerk training plan is located in Learning for reference, as well as the transcript for completion status.

Identification of associates in the pharmacy

State law requires that associates are properly identified in the pharmacy.

- For intern and technician identification requirements, see nametag requirements on the pharmacy portal page in the Pharmacy Manager section under **Ordering Nametags**.
- Also, all registrants must have a valid registration posted in the pharmacy in the designated area.

Prescription Documentation and Maintenance

Introduction

State and Federal regulations require that certain information be documented on prescription hard copies and also require that they be maintained following specific guidelines.

Prescription documentation

Certain information specified by state and Federal regulations must be documented on prescription hard copies or in our pharmacy system (via notes) relative to each prescription. In addition, Publix has contracts with third-party insurance plans that identify requirements for prescriptions in order for Publix to receive payment from the insurance plan.

Each Publix Pharmacy has access to the state Board of Pharmacy laws and rules, as well as the applicable Federal laws and rules which contain guidance on these topics. Publix maintains the following references that cover the basics; however, when unsure of a requirement, refer to the state or Federal laws and rules.

- **Reception Basics** document (pharmacy portal page *Pharmacy Operations > Quick References >Workflow > Reception Basics*), and
- **Medicare Part B Billing** document (*Pharmacy Operations > Quick References >Billing/Third Party > Medicare Part B Billing*) for reference that covers the basics.

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Prescription Documentation and Maintenance, Continued

Prescription (hard copy) maintenance

Each state and the DEA have different rules regarding hard copy maintenance. Publix has a hard copy handling and maintenance policy which meets the requirements of each state in which we operate.

See the chart below for our policy that meets each state's requirements.

State	Hard Copy tag requirements	Printing PPI for Rx Files Required?	Filing
Florida	Only hardy copy controlled substance prescriptions (CII – CV) are Hard Copy tagged.	No	• CIIs and CIII-CVs are filed separately in sequential Rx# order by 100. The Hard Copy tag is used to put the hard copies in sequential order. • Legends and OTCs are filed together by day.
Alabama	All hard copy prescriptions are Hard Copy tagged.	No	CIIs, CIII-CVs, Legends, OTCs are filed separately in sequential Rx# order by 100. The Hard Copy tag is used to put the hard copies in sequential order.
Georgia		No	
North Carolina		No	
South Carolina		No	
Tennessee		No	
Virginia		No	

Note: The Hard Copy tag is the label containing information required by state law to be on the back side of a prescription hard copy.

Note: With respect to controls, printing a PPI image and rescanning it places a non-original prescription on file and can be an audit risk. The rescanned image has a disclaimer "*Copy Only – Not Valid For Dispensing*". If you need to document any notes regarding a PPI prescription received for a control, this should be done via a Prescription Note (Rx Note) in EnterpriseRx.

Document retention

Publix retention guidelines comply with state, DEA and CMS requirements. Refer to the document retention guidelines on pg. 8-45, **Document Retention and Disposal**.

Handling ARNP and PA prescriptions

Introduction

ARNP's and PA's can write for non-controlled substances and sometimes for controlled substances depending on state regulations.

Summary of state requirements

If you receive a controlled substance Rx and are operating in a state that does not allow PA's or ARNP's to prescribe them, you must select the supervising prescriber as the MD in EnterpriseRx. See the related EnterpriseRx quick reference on the pharmacy portal page for processing information (*Pharmacy Operations > Quick References > Workflow >Data Entry).*

State	Nurse Practitioners	Physician's Assistant
Florida	Yes: CII-CV with a valid DEA (CII-Only for a 7 day supply and does not include psychiatric medication for children under 18 years old, **unless prescribed by an ARNP who is also a psychiatric nurse**.*) *The age and day supply limitations on CII psychiatric medications do not apply to ARNPs who are also licensed as psychiatric nurses, as defined in FL statute 394.455.	Yes: CII-CV with a valid DEA (CII-Only for a 7 day supply, and does not include psychiatric medication for children under 18 years old)
Georgia	Yes: CIII-CV with valid DEA	Yes: CIII-CV with valid DEA
Alabama	Yes: CII-CV with valid DEA & QACSC (Qualified Alabama Controlled Substance Certificate)	Yes: CII-CV with valid DEA& QACSC (Qualified Alabama Controlled Substance Certificate)
South Carolina	Yes: CIII-CV with valid DEA & state CSR (Controlled Substance Registration)	Yes: CII-CV with valid DEA & state CSR (Controlled Substance Registration)
North Carolina	Yes: CII-CV with valid DEA (CII's & CIII's are limited to a 30 day supply)	Yes: CII-CV with valid DEA (CII's & CIII's are limited to a 30 day supply)
Tennessee	Yes: CII-CV with valid DEA	Yes: CII-CV with valid DEA
Virginia	Yes: CII-CV with valid DEA	Yes: CII-CV with valid DEA (Must include name of supervising physician on the prescription. Does not need to be co-signed by the supervising physician.)

Pharmacist Prescribing (Florida pharmacists only)

Background

Florida pharmacists can prescribe certain prescription strength pharmaceuticals per Chapter 64B15-18 of the Florida Rules. In an effort to promote our Concierge level of service, we encourage our Florida pharmacists to prescribe from a select group of these products. It's important to follow the process described in this document to ensure compliance with the rules of the law.

Note: Pharmacist prescribing has not been approved for Publix pharmacists in other states.

Procedures

In the Concierge Services section on the Pharmacy page of Publix Connection there is a *Pharmacist Prescribing (FL only)* link where you can access the specific steps to properly prescribe and maintain records for these prescription orders. At this link there are also standard prescribing forms for each formulary drug which serves as the prescription hard copy and as documentation of specific patient information that must be gathered.

Key points

Only the pharmacist can prescribe or make recommendations (technicians and interns cannot be involved with the recommendation process).

Pharmacists may only prescribe to adults (≥ 18 years of age). The patient cannot be pregnant or nursing.

A copy of each prescription, with an appropriate back tag, must be maintained in a file folder labeled, *Pharmacist Prescribing (FL)* and retained according to the document retention guidelines on pg. 8-45, **Document Retention and Disposal.**

Publix Pharmacists are to prescribe ONLY from this limited formulary for the following indications:

- Anti-nausea: Scopolamine patches for motion sickness
- Oral analgesics: Naproxen Sodium 550mg for minor pain and menstrual cramps
- Topical anti-inflammatory: Hydrocortisone 2.5% cream for localized dermatitis not caused by infection
- Topical antiviral: Penciclovir (Denavir cream) for herpes simplex/labialis of the lips

Generic Substitutions and Orange Book Ratings

Introduction

Generics are usually less expensive than their brand-name equivalents. Because of this, some people tend to think that generics are in some way inferior to brand-name products. However, the Food and Drug Administration (FDA) requires that generic products meet the same quality standards as the brand name product. Generic manufacturers have to demonstrate the equivalency of the generic product to the brand name product in two areas:

- pharmaceutical equivalence (same dosage form, active ingredients, strength and route of administration), and
- therapeutic equivalence (same extent and rate of absorption of the active ingredients into the bloodstream).

Why dispense generics?

Pharmacists prefer to dispense generics. Some of the reasons are:

- Generics save patients money because they cost less than the brand-name equivalents.
- Generics help our pharmacies keep prescription prices competitive.
- Generics are sometimes required by third-party insurance plans. If a patient wants a brand name on a multiple-source product, their insurance may require them to pay a larger portion of the prescription cost.

State generic substitution laws

Generic substitution laws are state specific. In some states, substitution is strictly guided by the FDA's Orange Book (OB) rating system. In other states, the substitution laws are more flexible leaving it up to the pharmacist's judgement.

If the OB rating of a drug starts with an "A," it is equivalent. If the Orange Book rating starts with a B, the generic has not been determined to be equivalent to the brand. Not all of our states follow this coding system.

- Alabama, Tennessee, South Carolina, and Virginia require substitution according to the FDA's OB rating system.
- Florida, Georgia, and North Carolina do not require application of the OB ratings system when substituting for patients.

Selecting product in the pharmacy system

When selecting product in Data Entry, select the written product as documented on the prescription. When selecting the dispensed product in the system, first select the product you have in inventory or the preferred product. When you are selecting a generic substitution, ensure to select the one with the same OB rating as the brand in the states where this is required (AL, TN, SC, & VA).

Methamphetamine Abuse Regulations

Introduction

The U.S. Congress passed the USA PATRIOT Improvement and Reauthorization Act of 2005, which includes a number of provisions relating to the sales of products containing pseudoephedrine, ephedrine, and phenylpropanolamine. The President signed this legislation on March 9, 2006. Included in the Act are provisions concerning Methamphetamine, which impose certain restrictions and requirements with respect to the sale of pseudoephedrine, ephedrine, and phenylpropanolamine products.

Summary of Federal Law

This chart contains key elements of the Federal Law regarding methamphetamine abuse regulations.

Subject	Description
Affected Products	All pseudoephedrine (PSE), ephedrine (EPH), and phenylpropanolamine (PPA) products are classified under the Federal Controlled Substances Act (CSA) as "scheduled listed chemical products."
Product Restrictions	Non-liquid dosage forms (including gel caps) of the affected products must be in blister packaging or unit dose packaging, with no more than 2 dosage units per blister.
Sales Limits	Individual customer sales are limited to 3.6 gm/ day of PSE, EPH, or PPA base product. This daily sales limit is to be based on a calendar day.
Purchase Limits	Individual customer purchases are limited to 9 gm/ 30 day period of PSE, EPH, or PPA base product. This monthly purchase limit will be based on a calendar month. (The reference to a "purchase" limit means the responsibility to meet this limitation is on the customer. However, a retailer may not act recklessly in selling the products.)
Product Placement	Affected products must be stored behind a counter or in a locked cabinet.
ID Requirements	Consumers must show a federal or state issued photo ID, or an alternative form of ID acceptable by INS/DHS regulations, except for sales of PSE that are 60 mg or less, for which no ID requirement exists.

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Methamphetamine Abuse Regulations, Continued

Summary of Federal Law, cont'd

Subject	Description
Log and Other Recordkeeping Requirements	• Purchasers must sign a written or electronic log into which they have entered their name and address, and date and time of sale; and into which the seller has entered name and quantity of the product, except for sales of PSE that are 60 mg or less, for which there is no log requirement. • Log must be maintained for two years after date of last entry. • Privacy protections exist for information in the logs • Log must show a misrepresentation warning to purchaser; warning must include notice of maximum fine and term of imprisonment.
Training Requirements	• Individuals who deal directly with purchasers must undergo training provided by their employer. Employers must certify with Attorney General that all employees have been trained.

State Law Restrictions

Retailers must comply with state and local laws, as well. If there is a conflict between a provision of federal law and a state or local law, then Publix must comply with the most stringent provision.

Listed below are individual state restrictions that you should be aware of for the state in which you practice.

State	Law
Florida	• Product must be maintained and sold from behind the counter. • Purchaser must be at least 18 years of age. • See FL Code Ch. 893-1495.
North Carolina	• Product must be maintained and sold from behind the counter. • Purchaser must be at least 18 years of age. • Retailer must post a sign in the area where PSE products are for sale stating: "North Carolina law strictly prohibits the purchase of more than 3.6 grams total of certain products containing pseudoephedrine per day, and more than 9 grams total of certain products containing pseudoephedrine within a 30-day period. This store will maintain a record of all sales of these products which may be accessible to law enforcement officers." • See NC Code § 90-113.50
South Carolina	• Product must be maintained and sold from behind the counter. • See SC Code § 44-53-398.

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Methamphetamine Abuse Regulations, Continued

State Law Restrictions, cont'd

State	Law

Alabama	• Individual customer purchases are limited to 7.5 gm/ 30 days of PSE, EPH, or PPA base product.
	• If a purchaser resides in another state and that state requires a prescription, then the purchase requires a prescription in AL.
	• Product must be maintained and sold from behind the counter.
	• Purchaser must be at least 18 years of age.
	• ID restrictions are a little more stringent only allowing:
	  • valid, unsuspended driver's license or non driver identification card issued by this state
	  • valid, unsuspended driver's license or non driver identification card issued by another state
	  • US passport
	  • Foreign Passport
	  • US Uniformed Services Privilege and Identification Card
	• See AL Code §20-2-190.

Georgia	• Whenever a pharmacy in Georgia receives, purchases, or otherwise gains access to products containing PSE from any wholesale distributor, such pharmacy must maintain copies of all invoices, receipts, and other records regarding PSE products for a minimum of 3 years from the date of receipt, purchase or access (GA Code 16-13-30.4). • Pharmacies must maintain an electronic or paper logbook and it must be maintained for 2-years. • Product must be maintained behind the counter and only sold by a registered pharmacist or registered intern under the direct supervision of a pharmacist. • See GA Rules 480-19-.03 through .05.
Tennessee	• Products containing EPH, PSE or PPA may only be dispensed in a licensed pharmacy and can be maintained, by law, behind the counter or in a locked cabinet within 25 feet and in view of the pharmacy. Note: At Publix, we choose to keep this product behind the counter. • Tennessee Law restricts individual sales to 5.76g/30 day period and 28.8 gm/year. This means there is more responsibility on the pharmacy staff to track the sales. • See TN Code § 39-17-431.
Virginia	• In addition to the daily and monthly Federal limits, Virginia limits sales to 28.8 gm/year. • Product must be maintained and sold from behind the counter

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Methamphetamine Abuse Regulations, Continued

Plan-o-gram for products

At Publix, PSE products must be maintained behind the pharmacy counter. Work with your Pharmacy Supervisor to determine the best location for displaying these items.

You are responsible for maintaining inventory of all items listed on the *OTC Core Item List* which includes PSE products. This list can be found on the Pharmacy page @ *Pharmacy Operations > Ordering Product > OTC Core Item List*. These products can be ordered through our wholesaler.

You are also responsible for maintaining and displaying PSE aisle cards for our customers when they are looking for product in the OTC aisle or display areas outside of your pharmacy.

Selling PSE

When processing the sale of PSE products in the states of Alabama, Florida, Georgia, North Carolina, South Carolina, and Tennessee, you must follow the requirements below.

- The sale must be entered into the National Precursor Log Exchange (NPLEx) before ringing up the sale and providing product to the customer. Use of the NPLEx system is required by state law. The NPLEx system will verify whether or not the purchase meets daily and monthly limits based on state and Federal laws.
  - The NPLEx website link is on the Home page of your pharmacy system.
  - Procedures for access and use of this website are posted on the Pharmacy page of Publix Connection @ *Pharmacy Operations > NPLEx Procedure*.
- Each pharmacy is required to maintain a log of all PSE sales using the Combat Meth Log (RC0270).
  - This Log contains the purchase date, NPLEx transaction number, seller's initials, and purchasers signature. This is required by law.
  - In each state the Log must be maintained in your pharmacy for two (2) years from date of last entry.
- The products have been flagged in our POS system. When a customer attempts to buy more than **ONE** item in a single transaction, the register will lock up and not allow the second item to scan. If more than one product is within the sales and purchase limits the second item must be rung up as a separate transaction.

Note: Do not use the "generic" Pharmacy Bar Code to ring these items up – the quantity limits set in the system will not apply properly.

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Methamphetamine Abuse Regulations, Continued

Equivalency Charts

Equivalency charts for the daily sales limits and monthly purchase limits for PSE, EPH or PPA containing products are located on the Pharmacy page of Publix Connection @ *Pharmacy Operations > NPLEx Procedure*.

Combat Meth logs

The information in the log book used in each state is subject to privacy protections. Logs should be stored behind the pharmacy counter, and pharmacy associates should cover information of other individuals when obtaining a purchaser's signature.

Note: The Combat Meth Log is orderable from Printing Services by accessing the Pharmacy Supply Order Form on the Publix Connection at: *Pharmacy → Useforms → Supplies/Equipment Useforms → Store Supplies → Pharmacy Supply Order Form*. (RC0270 COMBAT METH LOG)

iPledge Program

Introduction

Because of isotretinoin's potential to cause birth defects, the FDA set up the iPledge program. It is a special distribution program that allows the marketing and distribution of isotretinoin.

Overview of iPledge Program Requirements

Prescribers, patients, pharmacies, and manufacturers/wholesalers must follow specific requirements under the iPledge program.

Isotretinoin must only be

- prescribed by physicians who are registered and activated with the iPledge program
- dispensed from registered and activated pharmacies by pharmacists who have received authorization from iPledge
- received by registered patients actively enrolled in the program and
- delivered to pharmacies by registered manufacturers/wholesalers.

Responsible Site Pharmacist

All Pharmacy Managers must be designated as their store's Responsible Site Pharmacist. This Responsible Site Pharmacist

- registers with iPledge as the Responsible Site Pharmacist
- activates the pharmacy registration, initially and annually, and
- trains all on-site pharmacists to fill isotretinoin.

The Responsible Site Pharmacist can be changed at any time by accessing iPledge via telephone or internet.

Overview of use of Isotretinoin

Isotretinoin is used to treat severe recalcitrant nodular acne, and is limited to a maximum 30-day supply with no refills. It is teratogenic and must NOT be used by pregnant women, and is not to be shared. Women should not become pregnant within one month of discontinuing isotretinoin therapy.

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iPledge Program, Continued

Dispensing Procedures

Follow these steps to fill isotretinoin.

Step	Action
1	Enter the prescription information on the Data Entry Detail screen in EnterpriseRx.
2	Ensure the prescription is being filled for a 30 day supply with no refills.

3	Continue processing.
	If... / **Then...**
	Claim adjudicates successfully → • Review the message response for details
	• Document the "Do Not Dispense After Date"
	  • in a Transaction Note, and
	  • on the iPLEDGE bag tag sticker.
	• Go to step 4.
	Claim rejects → • Follow the rejection message.
	• If rejection is resolved, go to step 4.
	• If you are unable to obtain a RMA number, contact the pt., cancel and profile Rx
	Note: Use the iPLEDGE Rejections quick reference on Publix Connection or assistance as necessary: *Pharmacy → Pharmacy Operations → Quick References → Workflow → Adjudication Exception → iPLEDGE Rejections*

4	Count and label prescription. Note: The package comes in a blister pack that cannot be broken.
5	Pull, review and pass the special handling label to the Pharmacist in the basket with the prescription.
6	At *Verification*, the RPh • reviews the special handling label to ensure all steps were followed to meet iPLEDGE program requirements • verifies the Rx and validates the "Do Not Dispense After Date" is noted in a Tx Note and on the iPLEDGE sticker. • places "Do Not Dispense to Patient After" sticker on the bag tag slip • places the labeled product in the reconstitutable/isotretinoin holding area, and • places the bag with bag tag slip and Patient Receipt and Education (PRE) in the Will Call bin.

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iPledge Program, Continued

Dispensing Procedures, cont'd

Step	Action
7	At *Release to Patient*, the associate • pulls the labeled bag with *PRE* from the Will Call bin with MIX as the bin location on the bag tag • pulls the labeled product from the reconstitutable/isotretinoin holding area, and • provides to the pharmacist to verify.
8	At *Release to Patient*, the pharmacist • makes sure the "Do Not Dispense to Patient After" date has not passed • initials the Rx label and then bags the Rx for the associate to release to the patient.

Return to Stock Procedures

The Daily Return to Stock report includes isotretinoin products for females of reproductive potential and should be evaluated each day for items that have exceeded the "Do Not Dispense to Patient After" date.

If the Rx was partially filled, and the patient did not pick up the *Completion Fill* reverse the prescription and reprocess for partial amount.

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iPledge Program, Continued, Continued

iPLEDGE Non-Compliance Action Policy

The iPLEDGE Non-Compliance Action Policy was approved as a component of the isotretinoin Risk Evaluation and Mitigation Strategy (REMS) by the FDA. It sets forth an implementation program by which non-compliance by iPLEDGE pharmacies will be evaluated. The goal of this monitoring program is to eliminate fetal exposure to isotretinoin. This policy went into effect for pharmacies on Friday, September 14, 2012. In addition to the enhanced iPLEDGE monitoring, Publix will also be reviewing dispensing data proactively to ensure compliance.

What is considered non-compliance

Pharmacy Non-Compliance will be evaluated and identified by the following (but is not limited to):

- iPLEDGE patients will be asked if they received isotretinoin during their last prescription window
- iPLEDGE prescribers will be asked if they know if their iPLEDGE patient(s) received isotretinoin during their last prescription window, and
- iPLEDGE will analyze the data provided by patients and prescribers to determine if there was non-compliant pharmacy dispensing.

A **Notice of Non-Compliance** will be issued if the pharmacy:

- Did not train pharmacy associates or there is no evidence of training records.
- Sold or otherwise transferred drug to/from another pharmacy.
- Did not document the RMA number on the prescription.
- Did not document the "*Do Not Dispense to Patient After*" date on the prescription or on the bag sticker.
- Broke a blister pack.
- Pharmacy did not dispense medication and failed to reverse RMA in the iPLEDGE system.

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iPledge Program, Continued, Continued

What is considered non-compliance, cont'd

A **Warning** will be issued if the pharmacy:

- Did not use the iPLEDGE website to verify the Patient's iPLEDGE eligibility and dispensed the medication without an RMA number.
- Dispensed multiple prescriptions without obtaining new authorization for each dose.
- Dispensed prescription after prescription window expired.
- Dispensed more than a 30-day supply.
- Obtained drug from unauthorized source (e.g. internet, non-activated wholesaler).
- Dispensed prescription while in a status other than activated.
- Knowingly used an iPLEDGE ID other than their own when accessing iPLEDGE.
- Knowingly allowed another stakeholder to access iPLEDGE using their ID.

A **Suspension** will be issued if the pharmacy:

- Accumulates two **Warnings** in 60 Days – resulting in suspension from program for 30 days (corrective action plan due within 30 days of effective date of suspension).

A **Temporary Deactivation** will be issued if the pharmacy:

- Checked iPLEDGE, the prescription is denied, but the pharmacy still dispensed the prescription without an RMA.
- A corrective action plan not received within 30 days of the effective date of a suspension.

A **Permanent Deactivation** is the pharmacy's permanent removal from participation in iPLEDGE and will be issued if the pharmacy:

- refused to return undistributed/unsold drug after being placed on temporary deactivation, or after not choosing to reactivate, or as otherwise requested.
- accumulates two **Suspensions** in a six month period, or
- accumulates one **Warning** while in a **Suspended** status, or
- accumulates one **Warning** while in a **Temporary Deactivation** status.
- A corrective action plan was not received within 90 days of the effective date of temporary deactivation.
- An acceptable corrective action plan was not received within 180 days of the effective date of temporary deactivation.
- Pharmacy fails to implement Corrective Action, or the iPLEDGE Program sponsors determine that no future program compliance can be expected (e.g., refusal to provide requested documentation for an investigation).

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iPledge Program, Continued, Continued

Progressive Discipline

To ensure compliance with this program, we've implemented the following progressive discipline policy that will be based on a rolling 12-month period.

Any associate will receive the following discipline if found in violation of the iPLEDGE Non-Compliance Action policy:

Written Counseling –

- Causes the pharmacy to receive one (1) **Warning** from iPLEDGE

1 Week Suspension –

- Causes the pharmacy to receive two (2) **Warnings** from iPLEDGE, or
- Causes the pharmacy to receive a **Suspension** from iPLEDGE

Termination –

- Causes the pharmacy to receive three (3) **Warnings** from iPLEDGE, or
- Causes the pharmacy to receive two (2) **Suspensions** from iPLEDGE, or
- Causes the pharmacy to receive one (1) **Temporary Deactivation** from iPLEDGE, or
- Causes the pharmacy to receive one (1) **Permanent Deactivation** from iPLEDGE

The Pharmacy Manager will receive the following discipline if any of their associates are found in violation of the iPLEDGE Non-Compliance Action policy:

Oral Counseling

- If their pharmacy accumulates one (1) **Warning** from iPLEDGE.

Written Counseling –

- If their pharmacy accumulates two (2) **Warnings** from iPLEDGE, or
- If their pharmacy accumulates one (1) **Suspension** from iPLEDGE.

1 Week Suspension –

- If their pharmacy accumulates three (3) **Warnings** from iPLEDGE, or
- If their pharmacy accumulates two (2) **Suspensions** from iPLEDGE, or
- If their pharmacy accumulates one (1) **Temporary Deactivation**.

Termination –

- If their pharmacy accumulates one (1) **Permanent Deactivation** from iPLEDGE.

Note: Whenever there is a non-compliant occurrence, the associate(s) involved must retake the iPLEDGE CBT within 7 days of discovery.

Ordering Supplies

Additional supplies, including *Do Not Dispense to Patient After* stickers and program brochures, can be ordered by accessing the **Order Materials** link on the iPLEDGE website.

Fraud and Abuse - Overview

Introduction

Publix Pharmacy is committed to its role in preventing and eliminating healthcare fraud and abuse. Our failure to observe healthcare fraud and abuse laws can result in serious consequences for Publix and Publix associates, including termination of employment, civil penalties, exclusion from participation in federal healthcare programs, criminal prosecution, and damage to Publix's reputation.

Definition of fraud and abuse

The Centers for Medicare and Medicaid Services (CMS) is the federal agency responsible for overseeing the financial integrity of the Medicare program and the states' Medicaid fraud and abuse control activities. CMS defines fraud and abuse as follows:

Fraud. The intentional deception or misrepresentation that an individual knows to be false (or does not believe to be true) and makes, knowing that the deception could result in an unauthorized benefit to himself or another person.

Abuse. Incidents or practices of healthcare providers that are inconsistent with sound medical practice and that may result in unnecessary costs, improper payments, or the payment for services that either fail to meet professionally recognized standards of care or that are medically unnecessary.

Examples of suspected healthcare fraud and abuse associated with billing activities

Fraud and abuse conduct occurs when a healthcare provider intentionally defrauds the government through the submission of claims for payment. Fraud and abuse conduct does not include inadvertent or innocent billing mistakes. The following billing activities of pharmacies may be suspected instances of fraud and abuse:

- Billing for drugs or supplies that were not dispensed.
- Billing for brand name drugs when generic drugs were dispensed.
- Billing for drugs as "covered" under a benefit plan when "non-covered" drugs were dispensed.
- Billing for drug samples.
- Failing to reverse claims for unused, returned prescriptions.
- Improperly billing multiple payors for the same dispensed drugs or supplies.
- Routinely waiving beneficiary co-payments.
- Inflating the bills for drugs or supplies.
- Using improper procedure or product coding (upcoding or unbundling).
- Billing healthcare programs for ineligible beneficiaries.
- Billing for prescriptions that are filled but not dispensed, i.e., never picked up by the patient.

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Fraud and Abuse - Overview, Continued

Other examples of suspected healthcare fraud and abuse

The following activities, when performed in connection with the submission of pharmacy claims, may be suspected instances of healthcare fraud and abuse:

Prescription Drug Shorting. Providing less than the prescribed quantity and intentionally not informing the patient or making arrangements to provide the balance, but billing for the fully-prescribed amount.

Bait and Switch Pricing. Leading a beneficiary to believe that a drug will cost one price but, at the point of sale, charging the beneficiary a higher amount.

Prescription Forging or Altering. Altering existing prescriptions without the prescriber's permission in order to increase the quantity or number of refills.

Dispensing Expired or Adulterated Prescription Drugs. Dispensing drugs that are expired or that have not been stored or handled in accordance with manufacturer or U.S. Food and Drug Administration requirements.

Prescription Refill Errors. Providing the incorrect number of refills authorized by the prescribing provider.

Engaging in Illegal Remuneration Schemes. Offering or paying, or soliciting or receiving, unlawful remuneration to induce or reward the pharmacy to switch patients to different drugs, influence prescribers to prescribe different drugs or steer patients to certain health plans.

TrOOP Manipulation. Manipulating a beneficiary's true out of pocket costs ("TrOOP") to either push beneficiaries through a plan coverage gap before they are eligible, or manipulating TrOOP to keep a beneficiary in a plan coverage gap.

Failure to Offer Negotiated Prices. Failing to offer a Medicare Part D beneficiary the negotiated price for a Part D covered drug.

Failure to Adhere to CMS' Marketing Guidelines. Failing to follow CMS' instructions for pharmacies on the marketing 'do's and don'ts' of participating in and assisting beneficiaries with Medicare Part D plans.

Fraud and Abuse – Applicable Laws

Introduction

The federal government and certain states have enacted laws pertaining to the submission of false or fraudulent claims for payment by federal and state agencies or private payors. A violation of these false claims laws may result in criminal, civil, and administrative penalties. Government agencies have broad authority under these laws to investigate and prosecute potentially fraudulent conduct.

About the Federal Civil False Claims Act

The federal Civil False Claims Act (FCA) forbids knowing and willful false statements or representations made in connection with a claim for payment submitted to the U.S. Government (or its agents and contractors) including federal healthcare programs, such as Medicare or Medicaid. The FCA also forbids the knowing concealment or improper avoidance of an obligation to pay the U.S. Government when there is an established duty to do so. The FCA extends to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or in reckless disregard of the truth or falsity of the information.

Penalties under the FCA include fines from $5,500 to $11,000 per false claim, payment of treble damages, and exclusion from participation in federal healthcare programs.

The FCA contains a whistleblower provision, which allows someone (whistleblower) with actual knowledge of alleged FCA violations to file suit on the federal government's behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but if it declines to do so, the whistleblower still may pursue the suit. A whistleblower who prevails may qualify for 15 to 30 percent of the amount recovered on the government's behalf, as well as attorneys' fees and costs.

The FCA prohibits employers from retaliating against employees (or against agents and contractors of the employer) who lawfully file or participate in the prosecution of a whistleblower suit. An employee who suffers unlawful retaliation from his or her employer (e.g., discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in terms and conditions of employment because of lawful acts done by the employee) may receive certain relief such as back pay, reinstatement or compensation for damages sustained as a result of the improper discrimination.

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Fraud and Abuse – Applicable Laws, Continued

Alabama False Claims Act

The Alabama False Claims Act (AFCA) authorizes Alabama to bring criminal actions against persons who cause Alabama Medicaid to pay claims that are false or fraudulent.

AFCA forbids a person from knowingly presenting a false or fraudulent claim to Alabama Medicaid. The AFCA extends to individuals who make, cause, or assist in making a false claim that have actual knowledge of the falsity of the information.

Criminal penalties under the AFCA include a felony conviction, a fine up to $10,000 and imprisonment for 1 – 5 years.

Florida False Claims Act

The Florida False Claims Act (FFCA) authorizes Florida to bring civil actions against persons who cause the state, including Florida Medicaid, to pay claims that are false or fraudulent.

Similar to the FCA, FFCA forbids a person from knowingly presenting a false of fraudulent claim to a Florida agency, including Florida Medicaid. The FFCA extends to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or in reckless disregard of the truth or falsity of the information.

Penalties under the FFCA include fines from $5,500 to $11,000 per false claim, payment of treble damages, and the costs of any civil action brought to recover such penalties or damages.

The FFCA contains a whistleblower provision, which allows someone with actual knowledge of alleged FFCA violations to file suit on the state government's behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but if it declines to do so, the whistleblower still may pursue the suit.

The FFCA protects employees from retaliation (e.g., being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment) by their employer when the employee's actions are lawful under the FFCA.

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Fraud and Abuse – Applicable Laws, Continued

Georgia False Claims Act

The Georgia False Medicaid Claims Act (FMCA) authorizes Georgia to bring civil actions against persons who cause Georgia Medicaid to pay claims that are false or fraudulent.

Similar to the FCA, FMCA forbids a person from knowingly presenting a false or fraudulent claim for reimbursement to Georgia Medicaid. The FMCA extends to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or reckless disregard of the truth or falsity of the information.

Sanctions for violating FMCA include civil penalties between $5,500 and $11,000 for each false or fraudulent claim, treble damages and other civil fines.

The FMCA contains a whistleblower provision, which allows someone with actual knowledge of alleged FMCA violations to file civil suit on the state government's behalf. The Georgia Attorney General may intervene in an FMCA whistleblower suit; however, if the Attorney General elects not to intervene then the whistleblower has the right to conduct the civil action.

The FMCA protects employees from retaliation (e.g., being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment) by their employer when the employee's actions are lawful under the FMCA.

North Carolina False Claims Act

The North Carolina False Claims Act (NCFCA) and the Medical Assistance Provider False Claims Act (MFCA) authorize North Carolina to bring civil actions against persons who cause the state, including North Carolina Medicaid, to pay claims that are false or fraudulent.

Similar to the FCA, the NCFCA and MFCA forbid a person from knowingly presenting a false or fraudulent claim to a North Carolina agency, including North Carolina Medicaid. The NCFCA and MFCA extend to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or in reckless disregard of the truth or falsity of the information.

Penalties under the NCFCA include fines from $5,500 to $11,000 per false claim, payment of treble damages, and the costs of any civil action brought to recover such penalties or damages. Penalties under the MFCA include fines from $5,000 to $10,000, payment of treble damages, and the costs of any civil action brought to recover such penalties or damages.

The NCFCA contains a whistleblower provision, which allows someone with actual knowledge of alleged NCFCA violations to file suit on the state government's behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but if it declines to do so, the whistleblower still may pursue the suit.

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Fraud and Abuse – Applicable Laws, Continued

North Carolina False Claims Act, cont.

The NCFCA and MFCA protect employees from retaliation (e.g., being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment) by their employer when the employee's actions are lawful under the NCFCA or MFCA.

South Carolina False Claims Act

The South Carolina False Claims Act (SCFCA) authorizes South Carolina to bring criminal and civil actions against persons who cause the South Carolina Medicaid to pay claims that are false or fraudulent.

Similar to the FCA, the SCFCA forbids a person from knowingly presenting a false or fraudulent claim to South Carolina Medicaid. Penalties under the SCFCA include imprisonment for up to 3 years, and fines up to $1,000 per false claim. In addition, the Attorney General may bring a civil action to recover treble damages and the imposition of a civil penalty of up to $2,000 for each false claim.

Tennessee False Claims Act

The Tennessee False Claims Act (TFCA) and the Tennessee Medicaid False Claims Act (TMFCA) authorize Tennessee to bring civil actions against persons who cause the state, including TennCare, to pay claims that are false or fraudulent.

Similar to the FCA, the TFCA and TMFCA forbid a person from knowingly presenting a false or fraudulent claim to a Tennessee agency, including TennCare. The TFCA and TMFCA extend to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or in reckless disregard of the truth or falsity of the information.

Penalties under the TFCA include fines from $2,500 to $10,000 per false claim, payment of treble damages, and the costs of any civil action brought to recover such penalties or damages. Penalties under the TMFCA include fines from $5,000 to $25,000, payment of treble damages, and the costs of any civil action brought to recover such penalties or damages.

The TFCA and TMFCA contain a whistleblower provision, which allows someone with actual knowledge of alleged TFCA or TMFCA violations to file suit on the state government's behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but if it declines to do so, the whistleblower still may pursue the suit.

The TFCA protects employees from retaliation (e.g., being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment) by their employer when the employee's actions are lawful under the TFCA.

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Fraud and Abuse – Applicable Laws, Continued

Virginia False Claims Act

The Virginia False Claims Act (VAFCA) authorizes Virginia to bring civil actions against persons who cause any agency of the Commonwealth to pay claims that are false or fraudulent.

Penalties under the VAFCA include fines from $5,500 to $11,000 per false claim, payment of treble damages, and the costs of any civil action brought to recover such penalties or damages.

Fraud and Abuse – Prevention and Detection

Introduction

It's important to do our part to prevent and detect healthcare fraud and abuse at Publix.

Publix Non-Retaliation Policy

It is Publix's policy to carefully review every legitimate report of wrongdoing and to not take disciplinary action against an associate for reporting wrongdoing, in good faith, to Publix or to government officials.

Pharmacy Staff Responsibilities

Pharmacy staff at retail locations are expected to prevent and detect fraud and abuse by:

- completing Fraud, Waste and Abuse required training within 7-days of hire and annually thereafter, according to the training curriculum established for each job class;
- following key billing procedures covered in your new hire training, quick references in the Pharmacy Operations section of the pharmacy portal page, and other reference materials included on the pharmacy portal page in *Concierge Services > Prescription Services > Billing*;
- calling our centralized support desk for pharmacy billing assistance (863-688-1188, x54004, option 4);
- complying with Publix's Code of Conduct (see your Associate Handbook or your store's *Managers' Reference Library*);
- complying with Publix's Code of Ethics (see your Associate Handbook or your store's *Managers' Reference Library*, as well as page 8-2 in the *Pharmacy R&P Guide*) ; and
- reporting questionable fraud and abuse conduct occurring at the Pharmacy using the reporting mechanisms described below.

How to Report Questionable Activity

Publix requires each associate to report conduct that a reasonable person would believe to be healthcare fraud and abuse. Each associate may report any such suspected instances of fraud and abuse to his or her Pharmacy Supervisor or to the Publix Corporate Counsel department. An associate may also anonymously report suspected fraud and abuse to the Publix Ethics Hotline (1-866-747-3773).

Fraud and Abuse – Investigate, Correct, and Report

Introduction

It is Publix's policy to conduct a timely and well-documented inquiry into any potential compliance incident or issue involving Medicare program noncompliance, fraud, waste, or abuse, including but not limited to the employment or engagement of excluded individuals.

Timely and reasonable inquiry

Regardless of how the noncompliance or FWA is identified, Publix's Compliance Officer (or designee) will initiate a reasonable inquiry, including a preliminary investigation as quickly as possible, but not later than two (2) weeks after the date the alleged noncompliance or fraud, waste, or abuse incident was identified.

Appropriate corrective action

Publix associates shall undertake appropriate corrective actions in response to confirmed noncompliance or confirmed fraud, waste, and abuse. Such corrective action shall be designed to correct the underlying problem that results in program violations and to prevent future noncompliance. Thorough documentation must be maintained of all deficiencies identified and corrective actions taken.

Reporting confirmed cases

The Publix Compliance Officer (or designee) shall report all confirmed program noncompliance, fraud, waste, or abuse, as required by Sponsor agreement or applicable law.

Tamper-Resistant Prescription Pads

Introduction

For Medicaid outpatient drugs to be reimbursable by the federal government, all written, non-electronic prescriptions must be executed on tamper-resistant pads. This requirement was included in section 7002(b) of the U.S. Troop Readiness, Veterans' Care and Katrina Recovery and Iraq Accountability Appropriations Act of 2007. The rule requires that the Medicaid programs have policies and procedures in place to support this requirement. Not doing so could lead to reduced funding for prescriptions from the federal government for the states.

Each state also has other requirements for tamper-resistant prescription blanks. In some cases requiring them for controlled substances or other insurance programs.

Important

Medicaid or other insurance companies can recoup monies from us for prescriptions that are not written on tamper-resistant prescription pads.

Characteristics of tamper-resistant prescription pads

There are three baseline characteristics of tamper-resistant prescription pads. The prescription must be written on paper that:

- prevents unauthorized copying of a completed or blank prescription form, or
- prevents the erasure or modification of information written on the prescription by the prescriber, or
- prevents the use of counterfeit prescription forms.

Exceptions

The law applies to written, fee-for-service Medicaid prescriptions or other prescriptions as identified by state law. Exceptions to this requirement include the following.

- Prescriptions received electronically (e-prescribing), via telephone or fax.
- Prescriptions for Medicaid eligible recipients enrolled in Managed Care Organizations (AVMED, AmeriGroup, Wellcare, PeachState, etc.)
- Prescriptions provided in nursing facilities or intermediate care facilities for the mentally retarded and the drug is reimbursed as part of the total service and is not reimbursed through the outpatient pharmacy program.

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Tamper-Resistant Prescription Pads, Continued

What are Tamper-Resistant Pads?

There are various tamper-resistant methods that use technology to create prescription pads that will show evidence of tampering. Below are some examples that are being used or may be used in the future.

- The following technology is used to detect unauthorized copying.
  - High-security watermark imbedded on the reverse side of the blank.
  - Thermochromic ink technology where a copied prescription blank shows the word 'Copy', 'Illegal' or 'Void.'
- Tamper-resistant background ink is used to detect erasures or attempts to modify written information on the prescription.
- Use of duplicate or triplicate blanks is used to prevent the use of counterfeit prescription forms.

Note: See example on the pharmacy portal page @ *References Government/Agency >Tamper-Resistant Prescriptions (Sample)*

State Rules

Each state website has documentation about the application of this regulation to prescriptions written in each state. See state Medicaid and BoP links on the pharmacy portal page for more information on your state requirements (*Concierge Services→ Prescription Services →Billing → Medicaid* and *References > Government/Agency > Boards of Pharmacy).*

State	Rules
Alabama	Prescriber can choose type of tamper-resistant pads as long as it complies with at least one of the three CMS characteristics.
Florida	A tamper-resistant prescription pad requirement is already in place for Medicaid prescriptions to meet all three CMS characteristics and should be used by prescribers. It is also required for all controlled substances.
Georgia	Prescriber can choose type of tamper-resistant pads as long as it complies with at least one of the three CMS characteristics. It is also required for CIIs.
South Carolina	Prescriber can choose type of tamper-resistant pads as long as it complies with at least one of the three CMS characteristics.
Tennessee	Prescriber can choose type of tamper-resistant pads as long as it complies with at least one of the three CMS characteristics. It is also required for **all** prescriptions. If you are unable to obtain a compliant prescription and as a result are unable to fill the prescription, you **must** provide the TennCare enrollee with a copy of the *Non-Tamper Resistant Notice* as required by the Grier Consent Decree. This explains and informs the enrollee of their right to an appeal. This is a special version of the Grier notice that only applies to Non-Tamper Resistant situations. Note: English and Spanish versions of the document can be downloaded from the TennCare website.
North Carolina	Prescriber can choose type of tamper-resistant pads as long as it complies with at least one of the three CMS characteristics.
Virginia	Prescriber can choose type of tamper-resistant pads as long as it complies with at least one of the three CMS characteristics. It is also required for prescriptions written for beneficiaries of FAMIS, VA's health insurance program for children.

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Tamper-Resistant Prescription Pads, Continued

Tips for assessing hard copy prescriptions against the requirements

Prescriptions that are computer-generated do not necessarily meet the tamper-resistant requirement unless they are printed on tamper-resistant paper. If you are not sure, you must confirm with the prescriber.

Prescriptions that are written in ink are not necessarily tamper-resistant, unless they are written on tamper-resistant paper. Ink is not an industry recognized standard for tamper-resistant.

Prescriptions written for individuals that are dually covered with a primary insurance and Medicaid must be written on tamper-resistant paper.

Prescriptions that are written for individuals with retroactive Medicaid coverage must comply with the tamper-resistant rule. Obtaining verbal confirmation from the prescriber and documenting it on the original prescription satisfies this requirement.

Prescriptions for Medicaid eligible individuals that are transferred between pharmacies orally, faxed or electronically are generally considered compliant if the original prescription was compliant.

Handling prescriptions that don't meet the requirements

If a prescription does not meet the tamper-resistant characteristics or you are unsure, contact the prescriber and explain the situation. Request from the prescriber a verbal, faxed, electronic or compliant written prescription.

You can fill the prescription(s) as long as the replacement is received within 72 hours. The 72 hour restriction only applies to the time for getting the compliant prescription, not to the amount of medication you can provide. You may dispense the prescription for the quantities and day supply indicated within the rules of the program.

Audit tip

If you take the prescription over the phone, make sure you document the name of the person you spoke with the date and time on the prescription. In the case of an audit or inspection, this documentation is critical. In the event that you attempt to obtain a compliant prescription, but are not successful, there is no provision to hold you harmless.

Document Retention and Disposal

Why this is important

Publix Pharmacies must retain certain pharmacy documents for specified time periods to comply with state, federal, and insurance requirements.

Time requirements

For a current list of Pharmacy Retention Requirements, go to Publix Connection *@ Resources > Records and Information Management > Retail Records Management > Pharmacy Retention Schedule*.

QRE document retention

The completed *Level 1 QRE Initial Report and Analysis* forms should be maintained until the next PPCQIP Quarterly Meeting behind the appropriate tab in your Information Binder.

Retain and dispose of QRE documents after the PPCQIP Quarterly Meeting according to the following chart:

State	After your PPCQIP Quarterly Meeting...
Florida	• shred the *Level 1 QRE Initial Report and Analysis* forms • file the *PPCQIP Meeting Agenda and Documentation* in your Pharmacy's Accordion File for 4-years making it available for inspectors if requested
Virginia	• shred the *Level 1 QRE Initial Report and Analysis* forms • file the *PPCQIP Meeting Agenda and Documentation & Level 1 QRE Summary* in your Pharmacy's Accordion File for 12-months making it available for inspectors if requested
All other states	• shred the *Level 1 QRE Initial Report and Analysis* forms • file the *PPCQIP Meeting Agenda and Documentation* behind the appropriate tab in the Information Binder and retain until the next quarterly meeting is conducted (after which it should be shred)

Shredding expired retained documents

Shred all retained Pharmacy documents once their retention deadline expires. All Pharmacies must go through this document disposal process at least twice a year.

The *Positive Formulary* and the *Negative Formulary*

Positive Formulary **(Florida only)**

The *Positive Formulary* lists all the preferred generic drugs that should be used in the Pharmacy. Publix Pharmacies receive generic drugs from the Publix Pharmacy Warehouse and from wholesalers. Wholesalers should only send us generic drugs listed on the *Positive Formulary*. You're required to make the *Positive Formulary* available to the public, Board of Pharmacy, or any physician who requests it.

This list is located in on the Pharmacy page of Publix Connection @ *References > Positive Formulary (FL).* It is useful for locating the

- brand name equivalent
- pack size and the NDC number
- A.W.P. rating (average wholesale price) and
- drug reorder number.

Negative Formulary **(Florida only)**

The *Negative Formulary* lists generic drugs that were not found to be the equivalent to the name brands by the Board of Pharmacy and the Board of Medicine.

Note: Florida is the only state Publix operates in that has a *Negative Formulary*. See the Florida Pharmacy's Laws (Rules) for a current list of negative formulary drugs.

Identifying Invalid Controlled Substance Prescriptions - Overview

Introduction

It's important to comply with Drug Enforcement Agency (DEA) and state regulations regarding the dispensing of controlled substances not only for the safety of your patients, but also to minimize consequences for Publix and Publix associates. To that end, Publix Pharmacy is committed to minimizing the dispensing of controlled substances based on fraudulent representations which is the focus of this policy.

Your responsibility

Fraudulent representations are situations where a prescription is deceptively presented to your pharmacy as a valid prescription when in reality it is an invalid prescription. An *invalid prescription* is one that a pharmacist knows or has reason to know was not issued for a legitimate medical purpose.

You are responsible for minimizing the dispensing of controlled substances based on fraudulent representations. This responsibility includes

- identifying and guarding against invalid practitioner-patient relationships
- guarding against filling fraudulent prescriptions for controlled substances
- identifying prescriptions that are communicated or transmitted illegally to avoid filling them
- identifying the characteristics of a forged or altered prescription to avoid filling them

Identifying Invalid Controlled Substance Prescriptions – Prescription Requirements

Introduction

To identify suspicious or fraudulent prescriptions, it's important to understand requirements associated with controlled substance prescriptions.

Requirements for controlled substance prescriptions

Pharmacy associates should know the requirements for a controlled substance prescription.

Schedule II

Schedule II prescriptions may be dispensed if the original hard copy of the written, signed prescription is presented to the pharmacy or if the pharmacy receives an e-prescription (see **Electronic transmission** section below).

See the DEA's website for the Code of Federal Regulations, section 1306.11, for exceptions. There are situations where a fax or oral prescriptions may be appropriate, but there are specific DEA requirements for handling these situations.

Also, refer to your state regulations.

Other Schedules

Schedule III, IV and V prescriptions may be dispensed with receipt of a written prescription, fax received directly from the prescriber's office, an oral prescription, or an e-prescribed prescription (see **Electronic transmission** section below).

See the DEA's website for the Code of Federal Regulations, section 1306.21, for exceptions.

Also, refer to your state regulations.

continued on next page

Identifying Invalid Controlled Substance Prescriptions – Prescription Requirements, Continued

Electronic transmission

Electronic Prescribing for Controlled Substances (EPCS) was developed by the DEA to provide pharmacies and prescribers with the ability to use traditional e-Prescribing with additional security measures to order new (Schedule II-V) and submit refill requests (Schedule III-V) for controlled substances. EPCS helps streamline the process to reduce risk of fraud and abuse from stolen prescription pads and/or forgery.

Not all Prescribers have the ability to electronically send and receive controlled substance prescriptions. Only the prescribers setup with the certified ePrescribing software, and who are individually certified can send and receive EPCS prescriptions.

When a new prescription is sent, before it enters workflow there are validation checks to make sure that the prescriber and prescription are valid.

Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing

Introduction

To minimize the dispensing of controlled substances based on fraudulent representations, it's important for a pharmacy associate to first identify suspicious or fraudulent prescription activity. If a pharmacy associate discovers a suspicious or fraudulent controlled substance prescription the pharmacist on duty should be notified and the prescription should not be filled until its validity can be verified.

Examples of suspicious activity or prescriptions

Always use professional judgment when assessing situations; however, consider this list of potential suspicious activity that may indicate an invalid controlled substance prescription is being presented to you in the pharmacy.

- The prescriber's practice is not near where the patient resides.
- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area.
- The patient appears impaired or his/her behavior is suspicious.
- The patient appears to be returning too frequently. (A prescription which should have lasted for a month in legitimate use, is being refilled on a biweekly, weekly or even a daily basis.)
- The patient requests early refills or states that the previous fill was lost or stolen.
- The patient changes prescribers frequently ("doctor shopping").
- The patient has multiple controlled substance prescriptions.
- A new patient presents a prescription for a large quantity of a controlled substance.
- The patient only pays cash for controlled substance prescriptions.
- The prescriber writes prescriptions for central nervous system (CNS) drugs, such as depressants and stimulants, at the same time. Some drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of patients appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous people who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same physician.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Types of fraudulent activity or prescriptions

Always use professional judgment when assessing situations; however, consider this list of potential ways that a fraudulent controlled substance prescription may be presented to you in the pharmacy.

- For those prescriptions required to be written on tamper resistant paper, a legitimate tamper resistant prescription pad could be stolen from a physician's office and used to write prescriptions for fictitious patients.
- A prescription could be altered by a patient in an effort to obtain additional amounts of legitimately prescribed drugs.
- A prescription pad from a legitimate doctor could be printed with a different call-back number where a drug abuser or accomplice verifies the prescription.
- A prescription could be called in by a drug abuser or accomplice providing their own telephone number as a call back confirmation.
- A prescription could be created from a home computer or a copy of a prescriber's legitimate prescription.

Identifying & guarding against invalid practitioner-patient relationships

Pharmacy associates should know how to identify an invalid practitioner-patient relationship. Some ways to do this are

- checking the prescriber's address to determine if it is the same general area as the patient's address
- checking the state's Prescription Drug Monitoring Program (PDMP) database to determine information such as frequency of fills, use of particular prescribers, dispensing of excessive quantities, filling at multiple pharmacies, etc.

  Note: If the pharmacy receives notice from the Florida PDMP program that within any 90-day period the patient has received prescriptions for controlled substances from more than one prescriber and had these prescriptions filled by five or more pharmacies, this indicates drug abuse as set forth in Rule 64K-1.007, FAC
- looking up the prescriber's contact information via another source and contacting the prescriber directly to validate the prescription.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Guarding against filling fraudulent prescriptions

Pharmacy associates should take the following actions in reviewing a controlled substance prescription.

- Carefully examine controlled substance prescriptions against the DEA and state requirements (see pg. 8-48).
- Evaluate that any faxed, transmitted, or orally prescribed prescriptions meet DEA and state requirements (see pg.8-48).
- Verify that controlled substance prescriptions are written on the required tamper resistant form when required by law.

  Note: For Florida, use the Approved Vendor Verification link on the Pharmacy page to assist you.
- Check the prescription to determine whether any information on the prescription has been altered.
- Check the prescriber's signature to make sure that it appears legitimate.
- For oral prescriptions, verify that the call came from the prescriber's office (e.g., if unsure or suspicious, call the office back using the phone number from our records).
- For oral prescriptions, verify that the caller is on the prescriber's staff (e.g., if unsure or suspicious, call the office back using the phone number from our records).
- For faxed prescriptions, make sure that the fax transmission came directly from the prescriber's office.
- Call the prescriber using the number on file if there are any questions.
- At pick-up, check the person's identification and verify that it is the person named on the prescription.

  Note: The states of Florida, South Carolina and North Carolina have more strict guidelines and are required to capture identification numbers in the pharmacy system. Reference **PDMP Reporting Requirements** on pg. 8-55 for further details. Also, see **Acceptable Photo ID's** on the pharmacy portal page *@ References→ Government/Agency→ Boards of Pharmacy & Government Agencies.*

Identifying prescriptions communicated or transmitted illegally

Pharmacy associates should carefully examine written, faxed or transmitted controlled substance prescriptions to try to ascertain if they are legitimate. Refer to the guidance in the above section, **Guarding against filling fraudulent prescriptions,** on pg. 8-52.

Note: All Florida and Georgia controlled substance prescriptions are required to be on tamper resistant prescription paper. Tennessee further requires all prescriptions to be on tamper resistant prescription paper. Also, CMS requires that all Medicaid prescriptions be on tamper resistant prescription paper – see more in the section on **Tamper-Resistant Prescription Pads** on pg. 8-42.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Identifying characteristics of a forged or altered prescriptions

Pharmacy associates should be able to identify characteristics of a forged or altered prescription. Some ways to do this are to determine if the

- prescription looks "too good" - the prescriber's handwriting is too legible
- prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations
- prescription appears to be photocopied
- directions are written in full with no abbreviations
- person other than the patient attempts to fill the prescription
- prescription is written in different color inks or written in different handwriting, or
- prescription is often paid for in cash.

Identifying Invalid Controlled Substance Prescriptions – Handling and Reporting

Introduction

It's important to properly handle a suspected invalid controlled substance prescription to protect Publix and comply with the law.

Handling a suspected invalid prescription

A pharmacy associate shall immediately notify the pharmacist on duty of any discovery of an attempt to obtain or instance where controlled substance was obtained through fraudulent methods or representations.

To determine validity of a prescription, the pharmacist must

- initiate communication with the patient or patient's representative to acquire appropriate information to determine validity, and
- initiate communication with the prescriber or prescriber's representative to acquire appropriate information to determine validity.

The pharmacist should also access the state PDMP website to acquire relevant information to determine validity.

If the pharmacist, using professional judgement, determines the prescription is invalid or cannot determine validity, the pharmacist shall refuse to fill or dispense the prescription.

Note: Pharmacists in Florida must complete a BoP-approved 2-hour continuing education (CE) course on the validation of prescriptions for controlled substances and counts toward the CE needed for license renewal.

Reporting of fraudulent prescriptions

Upon learning of any instance in which a person obtained or attempted to obtain from the pharmacy a controlled substance through fraudulent methods or representations, ensure the pharmacist on duty is notified. Then, the pharmacist on duty must notify the Pharmacy Supervisor.

Prescription Drug Monitoring Programs (PDMP)

About PDMP

Each state we operate in has developed a Prescription Drug Monitoring Program (PDMP), which is an online database established to record all controlled substance prescriptions filled in the particular state. The database gives pharmacists the ability to look at a patient's purchase history of controlled substances. Pharmacists can then use the information to make professional judgments about whether or not to fill a controlled substance for a patient.

Publix expectations for PDMP use

In the state of Florida, pharmacists must check the PDMP website prior to dispensing CII, CIII, CIV, and opioid CV (including refills) to patients 16 years and older.

In the state of Tennessee, pharmacists must check the PDMP Prior to dispensing a new opioid or benzodiazepine scheduled as a CII-CV.

In all other states, Publix Pharmacists must at a minimum create a personal account and use the website database to identify whether or not dispensing certain controlled substance prescriptions is appropriate. Some circumstances where using the database is recommended are listed below:

- new patient to Publix with a prescription for a large quantity of a controlled substance
- patient paying cash for controlled substance prescriptions
- patient with multiple controlled substance prescriptions
- patient requesting early refill or stating a previous fill was lost or stolen
- patient appears impaired or behavior is suspicious
- any time you feel in your professional judgment as a Pharmacist that it is necessary to check the patient's history

You can access the PDMP for your state from your EnterpriseRx home page, under: *Links→ Reference Links→ [State] Prescription Drug Monitoring Program.*

PDMP Reporting Requirements

Each state has different requirements for reporting to the PDMP. Florida, South Carolina and North Carolina law incorporates a requirement to check and capture photo identification information at pick-up in certain situations. This has been integrated into EnterpriseRx in the form of a pop-up at Release to Patient (RTP).

In this step, you will be required to capture pick-up person's name, identification type, number and jurisdiction, as well as relationship to the patient.

For Florida, you can refer to the FL Retail Pharmacy Controlled Substance Law Update and the FL Hospital Pharmacy Controlled Substance Law Update for detailed information. These are located on the pharmacy portal page @ *References→ Government/Agency→ Boards of Pharmacy & Government Agencies*

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Prescription Drug Monitoring Programs (PDMP), Continued

Handling PDMP results

When referencing the PDMP database use your professional/clinical judgement, regarding how to handle a prescription.

In Florida, if you choose to fill the prescription after reviewing the patient's history in the database, document your decision in a Tx Note.

- If you choose to fill the prescription, document your decision as "PDMP Checked- RX Accepted" in a Tx Note..
- If you choose not to fill the prescription and this is an *existing customer*, document your decision as "PDMP Checked- RX Rejected" in a Tx Note.
- If you choose not to fill the prescription and this is not an existing customer who is not in our system, no further action is needed.

If you are unable to check the PDMP due to the system being down or other technical issue, be sure to document "Unable to Check PDMP- System down/ Technical issue" in a Tx Note. In this case, Florida is limited to a max of a 3-day supply as required by law. Use your best judgement for all other states.

In Tennessee, since the PDMP must be checked for first fills. The following notes should be used but documented in an *RX Note*:

- "PDMP Checked- RX Accepted": if you choose to fill the prescription after checking the PDMP.
- "PDMP Checked- RX Rejected": if you choose to not fill the prescription after checking the PDMP.
- "Unable to Check PDMP- System down/ Technical issue": if the system is down or there is a technical issue. In this situation in the state of Tennessee, the pharmacist needs to use judgement regarding the decision to dispense or not considering other parameters.

Never print or provide the patient a copy of their Patient Advisory Report (PAR), which is generated from the database by practitioners/dispensers and contains controlled substance dispensing information for a specific patient. It is for informational purposes only.

Loss Prevention Investigations

Introduction

As part of an investigation, a Publix Loss Prevention Specialist may request a minimum necessary amount of an associate's prescription information from the Pharmacy. Providing an associate's prescription information is an allowable disclosure of PHI under the Privacy Rules, as it is considered part of health care operations (conducting or arranging for medical review, legal, and auditing services, including fraud and abuse detection and compliance programs). The Pharmacy is not required to account for PHI disclosures of this type.

Providing an associate's prescription information to a Loss Prevention Specialist

Follow these steps to provide an associate's prescription information to a Loss Prevention Specialist.

Note: Be sure to only provide the minimum necessary amount of information needed to conduct the investigation. For example, only provide the prescription date and prescription cost if that's enough information to conduct the investigation. Do not provide the prescription name unless it is needed for the investigation and the request has been approved.

<table>
<tr><th>Step</th><th>Who</th><th>Action</th></tr>
<tr><td>1</td><td>Loss Prevention Specialist</td><td>Request an associate's prescription information needed to conduct an investigation. Is the prescription name needed?<table><tr><th>If...</th><th>Then...</th></tr><tr><td>yes</td><td>contact the Pharmacy Supervisor and Privacy Officer for approval. Go to step 2.</td></tr><tr><td>no</td><td>go to step 3.</td></tr></table></td></tr>
<tr><td>2</td><td></td><td>Did the Pharmacy Supervisor and Privacy Officer approve the request for the prescription name?<table><tr><th>If...</th><th>Then...</th></tr><tr><td>yes</td><td>the Pharmacy Supervisor will notify the Pharmacist that he or she can release the prescription name. Go to step 3.</td></tr><tr><td>no</td><td>the Pharmacist cannot supply the prescription name. The investigation will need to be conducted without the use of the prescription name.</td></tr></table></td></tr>
<tr><td>3</td><td>Pharmacist</td><td>Receive request and provide the Loss Prevention Specialist with the requested prescription information.</td></tr>
<tr><td>4</td><td>Loss Prevention Specialist</td><td>Conduct the investigation and secure the prescription information obtained during the investigation.
Note: Always store Confidential Incident Reports and all supporting documentation in a locked file cabinet.</td></tr>
</table>

Losses and Theft of Controlled Substances

Introduction

We're legally obligated to report thefts and/or significant losses of controlled substances to the DEA and the state Board of Pharmacy. In addition, depending on state regulations, other agencies may need to be notified.

Immediate reporting of suspected thefts and/or significant losses to the DEA

Contact your Pharmacy Supervisor to help you determine whether a loss is "significant."

Thefts and/or significant losses must be reported to the DEA within one business day of discovery. **Contact your Pharmacy Supervisor** to prepare the report. It should be a short statement that is faxed to the local DEA office.

Reporting thefts and/or significant losses to the DEA using Form 106

Once circumstances surrounding the theft and/or significant loss are clear the DEA should be notified using *DEA Form 106*. **Contact your Pharmacy Supervisor** to help you complete the *DEA Form 106*.

Note: The *DEA Form 106* can be found on the DEA website. Once on the Pharmacy page of Publix Connection, go to *References > Pharmacy Boards and Government Agencies > DEA – Diversion Control Program*. Then on the DEA's website find the DEA Form 106 in the Quick Links section. Once you begin the form it will ask for:

- your pharmacy's DEA number, and
- the pharmacy name on DEA registration.

Reporting thefts and/or significant losses to Loss Prevention

Thefts and/or significant losses of controlled substances should also be reported to Publix's Loss Prevention Department with the help of your Pharmacy Supervisor. This chart provides contact information for Loss Prevention.

Division	Contact	Phone Number
Atlanta	Mike Zilleox	Office – (770) 952-6601, ext. 31734 Cell – (404) 456-1887
Charlotte	Patty Morgan	Office – (704) 424-5017, ext. 71068 Cell – (863) 370-0817
Jacksonville	Nolan Bomar	Office – (904) 781-8600, ext. 2478 Cell – (904) 370-4745
Lakeland	Faith Clark	Office – (863) 687-7407, ext. 64510 Cell – (863) 559-0223
Miami	Josh Edelstein	Office – (305) 653-1806 ext. 71339 Cell – (954) 594-2339

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Losses and Theft of Controlled Substances, Continued

Reporting thefts and/or significant losses

Once circumstances surrounding the theft and/or significant loss are clear you may be required to notify other agencies. **Contact your Pharmacy Supervisor** to help you determine this.

State	Requirements
Alabama	• In the event of a theft/significant loss, provide a copy of DEA Form 106 to the AL Board of Pharmacy. No time period for reporting is defined by rule or statute, but the expectation is that it would be reported contemporaneous with the DEA being notified. Ala. Admin. Code §680-X-3-.07. • In the event of a loss or theft of precursor chemicals, must report to the AL Board of Pharmacy no later than the 3rd business day after discovery of loss/theft. Code of Ala. §20-2-186.
Florida	• Report to the local sheriff within 24 hours after discovery of significant loss/theft. Fla. Stat. §893.07(5)(b) • Report to the FL Board of Pharmacy within 1 business day after discovery of significant loss/theft. Fla. Stat. §465.022(11)(b).
Georgia	• Immediately notify the GA Board of Pharmacy of any theft or loss of drugs or devices. This is not limited to "significant losses" nor to controlled substances. O.C.G.A. §26-4-112(4). • With respect to controlled substances, any loss or theft must be reported to the GA Board of Pharmacy and the GDNA within 72 hours of discovery. The report should be made on DEA Form 106. This is not limited to "significant losses." GDNA also requires a final report resulting from the associated audit/investigation within 72 hours of completion of the audit/investigation. Ga. Comp. R. & Regs. §480-16-.06 and §480-28-.10.
North Carolina	Report to the NC Board of Pharmacy within 10 days of the loss/theft, using the Drug Disaster and Loss Report (http://www.ncbop.org/Forms/DrugDisasterandLossReport.pdf). Statute and reporting form do not limit this to "significant losses" nor controlled substances. N.C. Gen. Stat. §90-85.25(b).
South Carolina	• Report theft or loss of drugs or devices to the SC Board of Pharmacy within 30 "working" days of discovery. S.C. Code Ann. §40-43-91(A)(1) • Report theft or any loss of controlled substances to the DHEC, Bureau of Drug Control, within 30 days of discovery. This is not limited to "significant losses". S.C. Code of Reg. R. 61-4.408. • A report of theft or "significant loss" should be submitted to DHEC on DEA Form 106. Any unexplainable losses should be reported to the supervisor.
Tennessee	Any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials must be "immediately" reported to the TN Board of Pharmacy. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged. This is not limited to "significant losses" nor to controlled substances. Tenn. Comp. R. & Regs. R. 1140-03-.09
Virginia	Upon discovery of theft or unusual loss of any controlled substance, the VA Board of Pharmacy must be immediately notified and within 30-days from discovery furnish details of the loss (e.g., list of medication, quantity, strengths). VA Pharmacy Act & Drug Control Act §54.1-3404.

Identifying and Handling Suspect Pharmacy Product

Introduction

Supply Chain security is of utmost importance to patient safety. Because of this, Publix only purchases product from manufacturers registered with the Food and Drug Administration (FDA), or wholesale distributors licensed under state or federal law. Unfortunately, suspicious product can still make its way into the legitimate supply chain. The following narrative describes Publix procedures for identifying and reporting suspicious/illegitimate product.

Definitions

Suspect product is defined by federal law as product for which there is reason to believe it:

(a) is potentially counterfeit, diverted, or stolen;
(b) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death;
(c) is potentially the subject of a fraudulent transaction; or
(d) appears otherwise unfit for dispensing such that the product would result in serious adverse health consequences or death.

Pharmacies who receive suspicious product must quarantine the product while they promptly conduct an investigation to determine whether the product is illegitimate.

Illegitimate product is defined as a product for which credible evidence shows that it:

(a) is counterfeit, diverted, or stolen;
(b) is intentionally adulterated such that the product would result in serious adverse health consequences or death;
(c) is the subject of a fraudulent transaction; or
(d) appears otherwise unfit for dispensing such that the product would result in serious adverse health consequences or death.

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Identifying and Handling Suspect Pharmacy Product, Continued

Identifying Suspect Product

The FDA provides recommendations on ways to identify suspect product:

- When receiving shipments, closely examine the package and look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).
- Closely examine the label on the individual items you receive, look for:
  - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
  - Any altered product information, such as smudged print or print that is very difficult to read.
  - Misspelled words.
  - Bubbling in the surface of a label.
  - Lack of an Rx symbol.
  - Foreign language with little or no English provided.
  - Foreign language that is used to describe the lot number.
  - A product name that differs from the name of the FDA-approved drug.

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Identifying and Handling Suspect Pharmacy Product, Continued

What to do if you identify suspect product

If you determine product is suspect, follow these steps:

Step	Action
1	Notify your Pharmacy Supervisor immediately.
2	Quarantine suspect product in an area to prevent intermingling with saleable and unsaleable inventory and wait for further direction from your Pharmacy Supervisor or the Pharmacy Procurement Department.
3	After further investigation, was the product determined to be illegitimate? **If...** / **Then...** No — Remove product from quarantine and place on your shelf for dispensing Yes — Go to step 4
4	Access FDA's Web page at: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm
5	Follow the instructions on the Web page for accessing Form FDA 3911. Using this form, provide information about • the person or entity initiating the notification, • the product determined to be illegitimate that is the subject of the notification to FDA, and • a description of the circumstances surrounding the event that prompted the notification.
6	Form FDA 3911 should be submitted by using the method provided on the form or on the Web page.
7	Print a copy for your records and store with your quarantined product. The FDA will now initiate an investigation. Wait for further communications.
8	Once the FDA responds, notify your Pharmacy Supervisor immediately. Has the FDA determined the product is illegitimate? **If...** / **Then...** No — Remove from quarantine and place on your shelf for dispensing Yes — If it is still deemed illegitimate, wait for guidance from your Pharmacy Supervisor.

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Identifying and Handling Suspect Pharmacy Product, Continued

Termination of Notification in Consultation with the FDA

If it has been determined that a notice of illegitimate product is no longer necessary and should be terminated, then pharmacies must follow these steps to notify the FDA. A notice of illegitimate product may only be terminated after notification to, and consultation with, the FDA has been completed.

Step	Action
1	Notify your Pharmacy Supervisor immediately.
2	Access FDA's Web page at: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm
3	Follow the instructions on the Web page for accessing Form FDA 3911. Using this form, provide • information about the person or entity initiating the request for termination, • the notification that was originally issued, and • an explanation about what actions have taken place or what information has become available that make the notification no longer necessary.
4	Form FDA 3911 should be submitted by using the method provided in the form or on the Web page.
5	FDA will review the request and respond within 10 business days. Continue to quarantine the product until the FDA responds.
6	Once the FDA responds, notify your Pharmacy Supervisor immediately. Has the FDA determined the product is illegitimate?

If...	Then...
No	Remove from quarantine and place on your shelf for dispensing.
Yes	If it is deemed illegitimate, wait for guidance from your Pharmacy Supervisor.

Handling Suspicious Packages

Summary

It's important to know what to do when you come across a suspicious substance or package that poses a concern of terrorist activity. Publix provides information on this process in the Retail Managers Reference Library (MRL) in the Loss Prevention and Security section.

Who to Contact

If you come across any suspicious substances or packages please contact your Store Manager immediately.

Suspect Product in the Pharmacy

Publix only purchases pharmacy product from manufacturers registered with the FDA or wholesale distributors licensed under State or Federal law. See *Identifying and Handling Suspect Pharmacy Product* in Chapter 8 of the Pharmacy R&P Guide for information about identifying and handling suspect pharmacy product (e.g., stolen, diverted).

Price Override Policy

Introduction

Publix offers cost savings programs for our patients; therefore price overrides in the pharmacy system are rarely approved.

Policy

Publix offers two cost-saving programs to our customers consisting of our FREE and $7.50 for up to a 90 day supply medications list. (See program information on Publix Connection on the pharmacy page @ Concierge Service > Prescription Services.) If you experience a pricing disparity or error, please continue to report it to Pharmacy Operations using the Pharmacy Non-Urgent Problem Reporting useform and select 'pricing issue' as the problem type.

Occasionally, a price override may be necessary for an over-the-counter medication that is not pricing properly in the pharmacy system. At which time, an override can be entered and new bag tag label can be printed from EnterpriseRx. Otherwise, price overrides are not part of our pricing policy.

Purchase Policy

Introduction

All Publix associates must pay the full retail price that Publix has established for their own purchases.

Policy

All products, including those ordered through our Pharmacy wholesaler and OTC items, must be purchased by associates for the full retail price and must not be discounted. This includes purchases for yourself or on behalf of others. You're not permitted to discount merchandise or accept discounted merchandise unless the merchandise is discounted by Publix.

The entire Purchase Policy is on page 3-15 of Your Associate Handbook. You can find the handbook on Publix Connection under *Resources* → *Benefits* → *Your Associate Handbook*.

Enforcement

Failure to pay the full retail price for any item will result in termination of employment.

Affordable Care Act – Non-Discrimination Rule

Introduction

The Department of Health and Human Services ("HHS") Office of Civil Rights ("OCR") has issued a final rule implementing Section 1557 of the Affordable Care Act. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. The substance of the rule is to ensure appropriate access to healthcare for all

This is an extension of the Americans with Disabilities Act (ADA) requiring that all of our customers have equal access to our stores, goods, services and communication. See the Managers Reference Library for more information on the ADA and how our company and associates comply with this regulation.

Protection of PHI and sensitive personal information

As always, in all communications whether at the counter or over the phone a patient's PHI and other sensitive information (e.g., credit card information) must be protected. See Ch.7 of the Pharmacy R&P for more about protecting patient's sensitive information.

Meaningful access for individuals with LEP

For those with limited English speaking proficiency (LEP), Publix must provide access to language assistance services that are accurate, free of charge and timely, while protecting privacy. When determining how to provide meaningful access for the patient, you must give primary consideration to the patient's request for assistance, and also consider the nature and importance of the information being discussed.

When oral interpretation is necessary, you must offer a qualified interpreter which Publix can provide through our language interpretation services solution. This can be offered at the counter or over the phone for your patients. However, these other options are also available to you:

1. You can rely on a pharmacy associate proficient in the patient's language if that is the patient's request.
2. You can rely on an accompanying adult to interpret if that is the patient's request, but you can not rely on a minor accompanying the patient except in an emergency or when there's no qualified interpreter immediately available.

For information on our language interpretation services, go to the following link on the pharmacy portal page of Publix Connection: *Pharmacy Operations > Language & Disability Services > Language Solutions*.

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Affordable Care Act – Non-Discrimination Rule, Continued

Effective communication for individuals with disabilities

For those with disabilities, Publix must take appropriate steps to ensure that communications are as effective as communications with patients without a disability. Auxiliary aids and services must be provided in accessible formats, free of charge, and in a timely manner while protecting privacy. The type of aid depends on the communication method used by the individual, the nature of the communication (complexity), and context. These are options available to you:

1. You can rely on an accompanying adult to interpret if that is the patient's request, but you can not rely on a minor accompanying the patient except in an emergency or when there's no qualified interpreter immediately available.
2. For information on our disability services, go to the following link on the pharmacy portal page of Publix Connection: Pharmacy *Operations* > *Language & Disability Services* > *Disability Solutions*.

Who to call for assistance

If you have a patient needing assistance and you are unsure how to assist the patient, immediately contact your Pharmacy Supervisor.

Affordable Care Act – Non-Discrimination Rule Grievance Procedure

Introduction

Any person who believes that an individual has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability during the solicitation or receipt of pharmacy services may file a grievance.

Filing the grievance

A grievance can be filed to the Publix Corporate Counsel Section 1557 Coordinator ("Coordinator") via mail to P.O. Box 407, Lakeland, Florida 33802-0407 or via fax to 863-413-5728.

Grievances must be submitted to the Coordinator in writing within sixty (60) days of the date the person filing the grievance becomes aware of the alleged discriminatory action. The grievance must state the name and address of the person filing the claim, the problem or action alleged to be discriminatory, and the remedy or relief sought.

Investigating the grievance

The Coordinator, or her or his designee, shall conduct an investigation of the grievance. This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant to the grievance. The Coordinator will maintain the files and records relating to such grievances.

Responding to the grievance

The Coordinator will issue a written decision on the grievance, no later than sixty (60) days after its filing, including a notice to the complainant of their right to appeal the written decision or pursue further legal remedies.

Publix does not tolerate retaliation

A person must not be retaliated against as a result of filing a grievance or engaging in protected legal activity. Any associate who retaliates against another person for a grievance is subject to disciplinary action, up to and including termination of employment. Any person who believes he or she is being retaliated against as a result of a grievance should inform the Coordinator. In addition, any person who believes a problem persists after the investigation has been completed should inform the Coordinator. These situations will be taken seriously, investigated, and action will be taken to resolve them, if appropriate.